Complete Summary

GUIDELINE TITLE

Guidelines for the management of colorectal cancer.

BIBLIOGRAPHIC SOURCE(S)

Association of Coloproctology of Great Britain and Ireland. Guidelines for the management of colorectal cancer. London (UK): Association of Coloproctology of Great Britain and Ireland; 2001. 87 p. [273 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Colorectal cancer

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Colon and Rectal Surgery
Family Practice
Gastroenterology
Internal Medicine
Oncology
Pathology
Radiation Oncology
Radiology
Surgery

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To assist clinicians in clinical decision-making and practice by removing uncertainty in areas where it is possible to do so
- To describe the gold standard of good clinical care and to proscribe unacceptable clinical standards

TARGET POPULATION

Patients of all ages who have or are at risk of developing colorectal cancer

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnostic Assessment

1. Clinical history and assessment of risk
2. Clinical examination (rectal, vaginal examination)
3. Flexible or rigid sigmoidoscopy
4. Double contrast barium enema
5. Colonoscopy
6. Pre-operative assessment of stage of disease
    - Assessment of rectum for local extension and peri-rectal lymph nodes using magnetic resonance imaging (MRI) or endorectal ultrasound
    - Assessment of chest and liver for metastases using computed tomography scan (CT) or MRI
7. Surveillance, genetic testing, and counseling for familial adenomatous polyposis (FAP) and hereditary non-polyposis colorectal cancer (HNPCC) families and other high-risk groups

Treatment/Management

1. Minimizing waiting times until treatment to 4 weeks or less

2. Delivery of care through multidisciplinary team (surgical specialist, oncologist, nurse specialist, radiologist, histopathologist)
3. Preparation for surgery
    - Obtaining informed consent
    - Preparation for stoma formation
    - Cross-matching for blood transfusion
    - Bowel preparation
    - Thromboembolism prophylaxis (subcutaneous heparin and/or intermittent compression)
    - Antibiotic prophylaxis
4. Surgery
    - Resection
    - Anastomotic technique
    - Abdomino-perineal excision
    - Local excision
    - Laparoscopic surgery
    - Record keeping
5. Management of patients presenting as emergencies
6. Measures to exclude pseudo-obstruction
7. Adjuvant chemotherapy
8. Adjuvant radiotherapy (preoperative and postoperative)
9. Treatment of advanced disease
    - Treatment of locoregional recurrence
    - Treatment of inoperable disease (primary chemotherapy and radiotherapy)
    - Treatment of metastatic disease (staging with CT scan, palliative chemotherapy, entry into clinical trials, 5-fluorouracil/irinotecan regimen, partial hepatectomy for liver metastasis)
    - Palliative care
10. Follow-up
    - Liver imaging
    - Colonoscopy
    - Facilitation of audit
    - Access to specialist nursing staff
11. Histopathology reporting

MAJOR OUTCOMES CONSIDERED

- Risk of colorectal cancer
- Sensitivity and specificity of diagnostic tests
- Rates of curative resection
- Operative mortality
- Wound infection
- Anastomotic dehiscence
- Recurrence rates
- Survival rates

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomized controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies such as comparative studies, correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

An initial steering group set up by the Royal College of Surgeons of England in 1994 decided to develop the guidelines using the following three approaches: i)

literature review in areas where unequivocal scientific bases for recommendations exist, ii) the results of contemporary audits of the management of all patients presenting with colorectal cancer in Trent, Wales and Wessex (see Appendix 1 in the original guideline document) in order to define reasonable practice where appropriate, and iii) consensus where no other approach is feasible or currently available. This has been complemented with the best results from the literature to provide "gold standards" at which to aim.

The original guidelines were drawn up by a small drafting committee, and revised by an expert advisory group composed of representatives of the main groups involved with the management of colorectal cancer. The revisions have followed a similar process of drafting and review by an expert advisory group.

Around the time the original guidelines were published two other documents appeared which had a significant impact on the provision of colorectal cancer care. These were the Calman Hine report and Guidance on Commissioning Cancer Services documents. (Department of Health 1995, NHS Executive 1997). These two documents have led to a significant change in the way in which colorectal cancer care is provided. This has changed the pattern of delivery of colorectal cancer care from being predominantly organised and delivered by individual surgeons to a multidisciplinary team (MDT) based approach. These revised guidelines reflect this change in approach and changes in patients' demands for greater information and a greater role in determining their treatment. These radical changes towards a more patient centred delivery of care are welcomed as an opportunity to improve the quality of care for patients with colorectal cancer.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grade of Recommendation

A. Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation (levels Ia, Ib)
B. Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendation (levels IIa, IIb, III).
C. Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates absence of directly applicable clinical studies of good quality (level IV)

Note: Every recommendation carries a grading according to this system. However, the grade cannot be regarded as an absolute indication of the strength of the guideline; although poor research has been omitted or flagged as such in the text, the cited studies are of variable quality. Thus, a guideline may have a grading which is not consistent with the evidence grading if the evidence is deemed to be unsatisfactory. Furthermore, some recommendations cover topics which are not amenable to formal studies but may represent good clinical practice (e.g., informed consent). These items have been labelled as "good clinical practice" and highlighted in the recommendations by the insertion of "GPP."

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations that follow are those from the guideline's summary; detailed recommendations can be found in the original guideline document. The grades of recommendations (A-C and GPP) and levels of evidence (Ia-IV) are defined at the end of the "Major Recommendations" field.

Investigation

It is recommended that patients with higher-risk symptoms should be fast-tracked either in special clinics or with urgent appointments to routine clinics. Patients referred through such clinics should be investigated with either flexible or rigid sigmoidoscopy plus a high quality double contrast barium enema or colonoscopy, when appropriate. B

Preoperative histology should be obtained from all rectal tumours. C

Doctors carrying out colonoscopy should audit their results, and expect to achieve a high total colonoscopy rate with a low perforation rate. B

It is acceptable for non-consultant staff to perform double contrast barium enemas, provided they have completed a recognised training programme and the examinations are performed to strict protocols and supervised by a consultant radiologist. C

All patients, particularly those with rectal cancer should have pre-operative staging to determine the local extent of the disease and the presence of lung and liver metastases. Endorectal ultrasound scanning should be performed to identify T1 rectal cancers, where local excision is being considered. Computed tomography (CT) or magnetic resonance imaging (MRI) scans should be undertaken to assess involvement of adjacent organs in more advanced tumours. C

Surveillance and genetic testing should be offered to all familial adenomatous polyposis (FAP) families and hereditary non-polyposis colorectal cancer (HNPCC) families that either meet the Amsterdam criteria or have a confirmed mismatch repair gene mutation. A

First degree relatives of patients who develop colorectal cancer before the age of 45 years and members of families in which multiple cancers have occurred should be seen by a specialist, preferably with experience in genetic counselling, who can evaluate their risk of developing the disease and advise on appropriate investigations and surveillance. B

Access to Treatment

Patients should expect to receive initial treatment within 4 weeks between making a diagnosis of colorectal cancer and start of therapy. B

Colorectal cancer should be treated by surgeons with appropriate training and experience and who work as part of a multidisciplinary team. GPP

All patients with colorectal cancer should have the benefit of a suitably informed surgical opinion and their management should be considered by the multidisciplinary team. GPP

Patients with colorectal cancer should have access to a colorectal nurse specialist for advice and support during their treatment. GPP

Preparation for Surgery

All patients undergoing surgery for colorectal cancer should give informed consent. Informed consent implies being given information about the likely benefits and risks of the proposed treatment and details of any alternatives. Informed consent should be obtained by the operating surgeon where possible. C

The patient who may require a stoma should be seen by a stoma nurse prior to surgery and the referral should be made at the earliest opportunity to allow adequate time for preparation. C

Blood should not be withheld if there is a clinical indication to give it, and preparations for blood transfusion should be made in all patients undergoing surgery for colorectal cancer except where an individual patient refuses. GPP

Mechanical bowel preparation prior to surgery is recommended. C

Subcutaneous heparin and/or intermittent compression should be employed as thromboembolism prophylaxis in surgery for colorectal cancer unless there is a specific contraindication. A

All patients undergoing surgery for colorectal cancer should have antibiotic prophylaxis. It is impossible to be dogmatic as regards the precise regime, but a single dose of appropriate intravenous antibiotics appears to be effective. A

Elective Surgical Treatment

It is recommended that the term curative resection should be based on histological confirmation of complete excision or residual tumour. Surgeons should

expect to achieve an overall curative resection rate of 60%, but it is appreciated that this will depend at least in part on the stage at which patients present. B

Any cancer whose distal margin is seen at 15 cm or less from the anal verge using a rigid sigmoidoscope should be classified as rectal. C

It is recommended that total mesorectal excision should be performed for cancer in the lower two thirds of the rectum, either as part of a low anterior resection or an abdomino-perineal resection (APER). In tumours of the upper rectum the mesorectum should be divided no less than 5 cm below the lower margin of the tumour. Care should be taken to preserve the pelvic autonomic nerves and plexuses, and perforation of the tumour during operation should be avoided. B

Although no definite recommendations can be made regarding anastomotic technique, the interrupted serosubmucosal method has the lowest reported leak rate and stapling facilitates ultra-low pelvic anastomoses. After anterior resection and total mesorectal excision the judicious use of a temporary defunctioning stoma is recommended, and the formation of a colonic pouch should be considered. B

Cytocidal washout of the rectal stump should be undertaken prior to anastomosis. GPP

The proportion of rectal cancers treated by abdomino-perineal excision of the rectum (APER) should be less than 40%, and, if distal clearance of 1 cm can be achieved, a low rectal cancer may be suitable for anterior resection. If a surgeon has any doubt regarding the choice between these two operations, an experienced second opinion should be sought. B

Local excision for cure in rectal cancer should be restricted to T1 cancers with well or moderate differentiation less that 3cm in diameter. It must be accepted that subsequent histopathological examination of cancers thought to be suitable for local excision will identify a small proportion which require more radical surgery. B

Laparoscopic surgery for colorectal cancer should only be performed by experienced laparoscopic surgeons who have been properly trained in colorectal surgery and who are entering their patients into one of the national trials. B

Record Keeping

There are existing guidelines for the keeping of clinical records issued by the Royal College of Surgeons and these should be adhered to for patients with colorectal cancer. C

A check-list should be used to construct an operation note for patients undergoing surgery for colorectal cancer. C

All patients with colorectal cancer should be brought to the attention of the Colorectal Multidisciplinary Team. Records of these meetings, the cases discussed, and the outcomes agreed must be recorded. GPP

Emergency Treatment

Emergency surgery should be carried out during daytime hours as far as possible, by experienced surgeons and anaesthetists. C

In patients presenting with obstruction, steps should be taken to exclude pseudo-obstruction before operation. B

Stoma formation should be carried out in the patient's interests only and not as a result of lack of experienced surgical staff. B

Adjuvant Therapy

Patients with Dukes C colon cancer should be considered for adjuvant chemotherapy. A

Patients with Dukes B colon cancer should be considered for entry into randomised trials of adjuvant chemotherapy. GPP

Patients with high-risk Dukes B colon cancer should be individually counselled about their level of risk and possible benefits of chemotherapy. GPP

There is no evidence to support the use of adjuvant chemotherapy in Dukes A cancers of colon or rectum. GPP

No definite recommendation can be made regarding adjuvant chemotherapy for patients with Dukes C rectal cancer. Patients may be either offered chemotherapy or be considered for clinical trials, in addition to appropriate adjuvant radiotherapy. B

Systemic chemotherapy should only be administered by clinical staff with appropriate training and experience, according to joint Council for Clinical Oncology (JCCO) guidelines. C

Patients with a mobile rectal cancer should be considered for entry into clinical trials of preoperative radiotherapy. C

Patients with rectal cancer in whom the tumour is tethered or in whom local imaging indicates a high risk of incomplete resection should be selected for long course pre-operative radiotherapy to obtain tumour downstaging. B

In patients with rectal cancer pre-operative radiotherapy using short course (25 Gy in 5 fractions in one week) or longer course (40-45 Gy in 20-25 fractions over 4-5 weeks) are both acceptable. A

In patients with rectal cancer who have not had pre-operative radiotherapy, post-operative radiotherapy and chemotherapy should be offered to patients with well established predictors of risk (e.g., evidence of tumour at the circumferential resection margins). A

In patients with rectal cancer, post-operative radiotherapy doses should be 40-50 Gy in 20-25 fractions or a suitable biological equivalent using a planned volume. B

A planned radiotherapy volume using three or four fields is recommended for rectal cancers as this results in less morbidity and mortality. B

Patients with potentially operable rectal cancer should always be considered for entry into trials of adjuvant radiotherapy. B

Treatment of Advanced Disease

For fit patients with inoperable rectal carcinoma without evidence of metastatic disease, primary radiotherapy alone or in combination with chemotherapy should be considered. B

Patients with metastatic disease who are fit for active therapy should be accurately staged with CT scans of abdomen and thorax. GPP

Patients with evidence of unresectable metastatic disease should be referred to an oncologist for consideration of palliative chemotherapy as soon as the diagnosis of metastatic disease is made, but this may not be appropriate for elderly patients. A

Chemotherapy for metastatic colorectal cancer should only be given after discussion at a Multidisciplinary Team meeting and under the direction of recognised clinical and medical oncologists within facilities conforming to JCCO guidelines. C

Entry into clinical trials evaluating the benefits of novel chemotherapy regimens in colorectal cancer should be encouraged. C

Palliative treatment should be 5-fluorouracil (5-FU) given by infusion combined with the use of irinotecan in the first line or on 5-FU failure if the patient remains fit for chemotherapy. A

Hepatic arterial infusional chemotherapy remains of unproven benefit. A

Patients with metastatic disease limited to the liver which is potentially resectable should be considered for partial hepatectomy by an experienced liver surgeon. B

Surgeons and oncologists who deal with colorectal cancer should make it a priority to build close links with palliative care specialists and units. B

All clinicians who deal with colorectal cancer should be trained in communication skills, in the control of pain and other cancer symptoms. C

It is important that patients with colorectal cancer are offered the opportunity to ask questions and to have important information repeated. Provision of information should be an essential part of every consultation. C

Outcome

Measurement of outcomes is an essential part of colorectal cancer care. In order to undertake measurement of outcomes, manpower resources and information technology (IT) facilities are required. These facilities are currently lacking in many hospitals.

Colorectal Cancer Units should carefully audit the outcome of treatment and achieve:

- An operative mortality of 15-25% for emergency surgery and 4-7% for elective surgery with colorectal cancer. B
- Intensive care and high dependency care are an essential part of peri-operative colorectal cancer care and should be available in hospitals undertaking colorectal cancer surgery. GPP
- Wound infection rates after surgery for colorectal cancer should be around 10%. A
- A clinical anastomotic leak rate of around 8% for anterior resections and around 4% for other types of resection. However ultra low pelvic anastomoses will have higher leak rates (around 15%) and therefore the judicious use of a defunctioning stoma is recommended. B
- Local recurrence rates after curative resection for rectal cancers should be around 10% within 2 years of follow up. B

Follow-Up

Although there is no evidence that intensive follow up for the detection of recurrent disease improves survival, it is reasonable to offer liver imaging to asymptomatic patients during the first two post-operative years for the purpose of detecting operable liver metastases. B

Although there is no evidence that colonoscopic follow-up improves survival, it has been shown to yield adenomatous polyps and cancers. If such a policy is pursued, it is recommended that a "clean" colon should be examined by colonoscopy at 3-5 year intervals. B

Follow-up is necessary for audit, which should be structured to determine post-operative mortality, anastomotic leak rates, colostomy rates, and 5-year survival. This should be regarded as a routine part of a Cancer Unit's work. C

All patients with a stoma should have ready access to specialist nursing staff. C

Histopathology

All resected polyps and cancers should be submitted for histopathological examination. B

Pathology reports should contain information on all of the data items contained in the Joint National Guidelines Minimum Data Set for Colorectal Cancer Histopathology Reports. C

Pathology laboratories should store stained histology slides for a minimum of 10 years, and tissue blocks from specimens indefinitely, in order to facilitate future case review, clinical audit, and research. B

Pathological examination of colorectal cancer specimens should be carried out in laboratories which perform to high technical standards such as those required for Clinical Pathology Accreditation, and participate in external quality assessment schemes and regular audit of technical procedures and diagnosis. B

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Consistent high quality care for patients with colorectal cancer

POTENTIAL HARMS

- Side effects of therapy
- Colonoscopy may result in possible discomfort and the risks of perforation and bleeding.
- Perforation of the tumour during resection is an important factor, as it is associated with local recurrence.
- Anastomotic dehiscence is a major source of operative morbidity and mortality after resection for colorectal cancer.
- Permanent stoma formation may occur following surgical intervention.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

It is important to stress, that guidelines are not intended to create a rigid framework where there is a reasonable difference of opinion. Thus, clinical freedom within limits defined by good practice is preserved.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Facilitation of Audit, Quality Assurance, and Clinical Governance

Audit is the only means by which clinical outcomes can be measured and it is likely to underpin the new initiative of clinical governance. Accurate, relevant, reliable data in which clinicians have confidence is an absolute prerequisite for audit and demands organised and disciplined methods of collection. The Association of Coloproctology of Great Britain and Ireland has produced a minimum data set which may help to overcome some, but not all, of the pitfalls in data collection for colorectal cancer audit. Fundamental to the data set is a data dictionary, which precisely defines each field to ensure conformity of interpretation. The data set and data dictionary are freely available on the internet

on www.canceruk.net/ . Data collection forms are included in Appendix 4 of the original guideline document. It is only by audit that surgeons can evaluate their results against professional standards. Information from audit provides the stimulus to investigate and perhaps modify personal practice.

If guidelines are to be of value, surgeons must audit their results, and for this some form of follow-up is essential. This might be by regular surgeon/patient contact or through review by clinical nurse specialists, primary care, or postal contact. In the absence of supportive evidence local circumstances may dictate local practice.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Chart Documentation/Checklists/Forms

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001

GUIDELINE DEVELOPER(S)

Association of Coloproctology of Britain and Ireland - Medical Specialty Society

SOURCE(S) OF FUNDING

Funding for the original guidelines was provided by a grant from the Department of Health to the Royal College of Surgeons of England. The revisions have been organised through the Association of Coloproctology of Great Britain and Ireland and funded by a charitable donation from Beating Bowel Cancer and by a donation from The Colon and Rectal Disease Research Foundation of Great Britain & Ireland.

GUIDELINE COMMITTEE

Expert Advisory Group Drafting Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Prof JH Scholefield (Chairman); Prof CG Marks; Dr TS Maughan; Prof NA Shepherd; Mr JD Stamatakis; Prof RJC Steele; Mr MR Thompson

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Association of Coloproctology of Britain and Ireland Web site.

Print copies: Available from the Association of Coloproctology of Britain and Ireland at The Royal College of Surgeons of England, 35-43 Lincoln's Inn Fields, London, WC2A 3PE

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Association of Coloproctology of Great Britain and Ireland colorectal data set and data dictionary. Electronic copies: Available from www.canceruk.net/.
- Additionally, data collection forms are available in Appendix 4 of the original guideline document. Electronic copies: Available in Portable Document Format (PDF) from the Association of Coloproctology of Britain and Ireland Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on June 27, 2005. The information was verified by the guideline developer on July 25, 2005.

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